Applicant elects Group I **without traverse**, and without waiving the right to prosecute the non-elected claims in another application.

The Examiner restricted Group I into the following **2 species**:

a) SEQ ID NO:1; and

b) SEQ ID NO:3.

Applicant **traverses** this requirement. Nonetheless, for the purpose of providing a complete response to the Restriction Requirement, Applicant elects SEQ ID NO:1.

2. TRAVERSAL

Applicant **traverses** the Examiner's requirement for election in Group I of SEQ ID NO:1 or SEQ ID NO:3 because (A) the Examiner has not met her burden of establishing that examining both SEQ ID NO:1 and NO:3 in a single application will create a serious burden on the PTO, and (B) Claim 5, which recites SEQ ID NOs:1 and 3, is a linking claim.

A. The Examiner Has Not Established A Serious Search Burden

The Examiner found that the "inventions are distinct, each from the other."[1] However, it is **not enough** that the Examiner allege distinctness of the claimed inventions. MPEP 808.02 directs the Examiner that she **also** "must show by appropriate explanation" one of the following: (1) a separate classification of the claimed inventions, (2) a separate status in the art when the inventions are classifiable together, and (3) a different field of search. The Examiner has not provided the requisite explanation for any one of these requirements as further discussed below.

1. A Separate Classification Is Not Shown

The Examiner did **not** advance **any** classification for the restricted sequences, let alone that the classification is separate. Thus, the first requirement for restriction is lacking.

The Examiner instead relied on the argument that the "different SEQ ID NOs. encompassed in group I are structurally and functionally distinct and are unrelated."[2] This is

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[1] Office Action, page 2.

[2] Office Action, page 2.

incorrect. The Specification discloses the **functional relatedness** of the recited "human decay accelerating factor" polypeptide sequences by teaching that:

> "It is also expressly contemplated that the term 'human decay accelerating factor' includes variants of SEQ ID NO:2 and/or SEQ ID NO:4 which have the **biological function** of SEQ ID NO:2 and/or SEQ ID NO:4, respectively."[3]

Since the Examiner's argument is incorrect, it cannot support her alleged finding that "a search for both sequences would encompass a burdensome search."[4]

2. A Separate Status Is Not Shown

With respect to the second ground for requiring restriction, *i.e.*, a separate status in the art, the Examiner must provide "an explanation [which] indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status."[5] However, the Examiner did **not** explain why SEQ ID NO:1 concerns a **separate inventive efforts** from SEQ ID NO:3. Indeed, the above-discussed related biological function of the proteins that are encoded by SEQ ID NOs:1 and 3 compels a contrary conclusion. Therefore, the second basis for insisting on restriction has not been satisfied.

3. A Different Field of Search Is Not Demonstrated

Considering the third basis for insisting upon restriction, (*i.e.*, different field of search), the Examiner must show that "it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists." However, **no** such showing is provided.

Because the necessity for restriction is not established under any one of the three alternatives, it is respectfully requested that restriction between the SEQ ID NO:1 and 3 be withdrawn.

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[3] Specification, page 18, last full paragraph.

[4] Office Action page 2.

[5] MPEP 808.02 (B).

B. Claim 5 Is A Linking Claim

Restriction is improper because Claim 5 is a **linking claim**. Under the restriction practice of the U.S. Patent & Trademark Office (PTO), linking claims

> "if allowed act to *prevent restriction* between inventions that can otherwise be shown to be divisible."[6] "The linking claims *must be examined* with the invention elected, and should any linking claim be allowed, *the restriction requirement must be withdrawn.*"[7]

The MPEP defines linking claims to include "genus claims linking species claims."[8] In the instant case, Claim 5 is a linking claim because it recites a genus of proteins (*i.e.*, the recited "human decay accelerating factor") that are encoded by, and that **link**, the species of encoding nucleic acid sequences (*i.e.*, the recited exemplary SEQ ID NOs: 1 and 3). In conformance with the PTO's practice with respect to linking claims, and since (as explained above) the Claims 5 is a linking genus claim that links the species of SEQ ID NOs: 1 and 3, Applicant respectfully requests **withdrawal of the restriction of SEQ ID NOs: 1 and 3.**

Further, the impropriety of the Examiner's requirement for election of a single species of a variant sequence is evidenced by the issuance of numerous U.S. patents that claim a genus of variant sequences. For instance, U.S. Patent No. 6,136,558, issued on October 24, 2000 to Ballinger *et al.* contains the following generic Claim 1 that recites variants of a defined sequence:

> "A variant of heregulin, said variant having an amino acid sequence not found in nature and the ability to bind an ErbB receptor, wherein said variant comprises a different amino acid than in said heregulin wherein: at residue number 177 said different amino acid is A, F, W, or Y; at residue number 178 said different amino acid is A, D, E, G, L, N, P, Q, R, T V, or W; at residue number 179 said different amino acid is A, G, L, M, P, S or V; at residue number 180 said different amino acid is A, D, E, G, H, I, K, M, N, P, Q, or R; at residue number 181 said different amino acid is A, G, I, L, P, or V; at residue number 183 said different amino acid is A, G, I, L, M, S, or T; at residue number 184 said different amino acid is A, F, G, H, I, K, L, M, N, P, Q, R, S, V, or W; at residue number 185 said different amino acid is A, G, H, I, K, L, M, N, P, Q, S, T, or V; at residue number 186 said different amino acid is A, K, R, or S; at residue number 187 said different amino acid is A, E,

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[6] (Emphasis added) MPEP 809.03.

[7] (Emphasis added) MPEP 809.

[8] MPEP 809.03; see also MPEP 809.02.

> G, I, L, M, N, P, Q, S, or T; at residue number 188 said different amino acid is A, H, K, N, or R; at residue number 195 said different amino acid is A, H, N, Q, R, or S; at residue number 197 said different amino acid is A, F, L, V, or W; at residue number 198 said different amino acid is A, H, K, R, or S; at residue number 200 said different amino acid is A, H, R, or S; at residue number 201 said different amino acid is G, H, I, L, M, P, R, S, T, or V; at residue number 205 said different amino acid is A, F, H, I, K, R, T, V, W, or Y; at residue number 206 said different amino acid is A, F, G, H, I, K, L, M, P, R, S, V, W, or Y; at residue number 207 said different amino acid is F, H, I, L, P, R, V, W, or Y; at residue number 208 said different amino acid is A, H, K, R, or S; at residue number 209 said different amino acid is G, M, P, S, T, or V; at residue number 211 said different amino acid is A, H, R, or S; at residue number 213 said different amino acid is A, C, D, E, F, G, H, I, K, L, M, N, P, Q, R, S, T, W, or Y; at residue number 214 said different amino acid is A, C, D, E, F, G, H, I, K, L, M, N, P, Q, R, S, T, W, or Y; at residue number 215 said different amino acid is A, C, D, F, H, I, K, L, M, N, P, Q, R, S, T, V, W, or Y; at residue number 216 said different amino acid is A, G, L, M, P, or V; at residue number 223 said different amino acid is A, F, H, R, S, or W; or at residue number 226 said different amino acid is A, G, L, or P; wherein said residue numbers correspond to residue numbers of native human heregulin-.beta.1 (SEQ ID NO: 93) numbered from the N-terminus; and wherein said heregulin variant comprises a portion that is at least 70% identical to the portion from about residue 175 to about residue 230 of native human heregulin-β1 (SEQ ID NO: 93)."

Similarly, U.S. Patent No. 6,271,010 issued on August 7, 2001 to Andersen *et al.* also contains the following generic Claim 1 that recites variants of a defined sequence:

> "A CGTase variant having an amino acid sequence which differs from the amino acid sequence of a parent CGTase, wherein the parent CGTase is a Thermoanaerobacter CGTase and the difference between the amino acid sequence of the CGTase variant and the amino acid sequence of the parent CGTase comprises one or more of the following: 47C; 47D; 47E; 47F; 47G; 47I; 47K; 47N; 47P; 47S; 47T; 47V; 47W; 47Y; 145D; 145H; 145I; 145N; 145Q; 145V; 146H, 146L; 146T; 146V; 146Y; 147C; 147E; 147N; 147Q; 196C; 196E; 196F; 196H; 196I; 196K; 196M; 196P; 196Q; 196R; 196T; 196V; 196W; 196Y; and 371C; 371F; 371H; 371K; 371M; 371R; 371T; 371W; wherein each position corresponds to the position of the amino acid sequence of the mature CGTase obtained from Bacillus circulans strain 251."

Yet another exemplary patent (U.S. Patent No. 6,111,081 issued on August 29, 2000 to Conneely *et al.*) contains the following generic Claim 1 that embodies variants of a defined sequence:

> "A nucleic acid sequence encoding a lactoferrin variant or portion thereof, wherein said portion is further defined to comprise an amino acid sequence corresponding to at least one iron binding site of lactoferrin, and wherein the

> lactoferrin variant or portion thereof has a modified iron binding capacity, and wherein the amino acid sequence corresponding to at least one iron binding site of lactoferrin comprises a mutation or deletion of one or more amino acids selected from the group consisting of Asp 396, Tyr 93. Tyr 193 and His 254 in the amino-terminal lobe and Asp 396. Tyr 436. Tyr 529 and His 598 in the carboxy-terminal lobe."

In view of the recent issuance of numerous U.S. Patents that contain linking generic claims that recite **variants** of sequences, and since the instant Claim 5 is a linking claim that is generic to variant sequences, it is respectfully requested that **the restriction of SEQ ID NOs: 1 and 3 be withdrawn**.

CONCLUSION

If a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call Dr. Maha A. Hamdan as indicated below.

Signed on behalf of:

Dated: January 31, 2003

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